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**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

CHURCH & DWIGHT CO., INC., a Delaware corporation,

Plaintiff,

v.

SPD SWISS PRECISION DIAGNOSTICS GmbH, a Swiss Corporation,

Defendant.

Case No. 14-CV-585 (AJN)

**PRETRIAL MEMORANDUM OF LAW
(Indv. Practices 5C)**

The Hon. Alison J. Nathan

Trial Date: April 20, 2015

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INTRODUCTION

Plaintiff Church & Dwight Co., Inc. ("C&D") claims that the advertising for the Clearblue Advanced Pregnancy Test with Weeks Estimator (the "Weeks Estimator" or "Product") is false because it conveys to consumers that the Product estimates weeks since the start of pregnancy. According to C&D, such a message is false because the Product estimates weeks since a pregnant woman ovulated, while the "universal convention" among doctors is that pregnancy is dated from the first day of a woman's last menstrual period ("LMP").

C&D's claims fail at every level. First, they are precluded as a matter of law because the U.S. Food & Drug Administration ("FDA") exercised its exclusive authority under the Food, Drug & Cosmetic Act ("FDCA") to control the challenged packaging and promotional materials on precisely this message and determined that the advertising will ***not*** mislead consumers as C&D has alleged. Indeed, when C&D complained directly to the FDA, the FDA considered C&D's allegations and – despite clear authority to judge the advertising false and order it to stop for exactly the reasons C&D is alleging before this Court – ***declined*** to take that action. Instead, the FDA approved the packaging and core advertising C&D challenges in this lawsuit. In directly conflicting with the FDA's statutory determinations, C&D's claim is barred.

Second, as a matter of undisputed fact, the Product ***does*** estimate weeks since the start of pregnancy. Indeed, medical science recognizes the time of ovulation as the "gold standard" for dating pregnancy. That is because, as a matter of established biology, pregnancy begins at fertilization of the ovum, which occurs within 24 hours after ovulation (the release of the egg from a woman's ovary). Accordingly, any message that the Product estimates the start of pregnancy is absolutely true.

C&D's theory that weeks since the start of pregnancy is synonymous with weeks since LMP – and not weeks since ovulation – is wrong. While doctors developed a convention of

dating pregnancy from a woman's LMP prior to the advent of technologies that determine when ovulation/fertilization occurred, the medical community has long understood that a woman cannot actually be pregnant at her LMP. At that point, she is menstruating and, on average, two weeks from the event that is necessary for pregnancy to occur: ovulation. Indeed, now that the time of ovulation can be determined, the guidance of authoritative medical publications and the widespread clinical practice of doctors is that, when the date of ovulation is known, it should be used to date the pregnancy. While that dating is sometimes *converted* to the still-common LMP convention by adding two weeks to the date of ovulation (regardless of when actual LMP occurred), doctors fully understand that pregnancy itself started at ovulation/fertilization.

This raises the third reason C&D's claim is meritless. C&D's claim assumes, without any evidence whatsoever, that the challenged advertising communicates that the Week Estimator is estimating weeks since LMP (or, as C&D puts it, the same way a doctor does). But the only messages on the challenged packaging and other advertising say the *opposite*. Indeed, the FDA required disclosures on the packaging and all promotional materials that the Product estimate is *different from* the LMP convention. The FDA even required inclusion of a conversion chart in the Product instructions showing the two-week difference.

Despite the absence of any literal message that the Product estimates weeks from LMP (and plenty of contrary express messages), C&D offered no survey evidence aimed at determining whether women are nonetheless receiving such a message. Rather, its two survey experts *expressly assumed* that "weeks of pregnancy" and "weeks since LMP" are one and the same, even though that is biologically incorrect. Their surveys are thus entirely meaningless in carrying C&D's burden of showing that women received a false message.

Moreover, there is no evidence whatsoever that women are ignorant of the fact the fertilization (commonly referred to as "conception") marks the beginning of pregnancy. To the

contrary, the only evidence on that subject supports the opposite conclusion: women fully understand that conception occurs near the time of ovulation. Indeed, millions of women now buy home ovulation tests – including C&D's First Response brand – for the purpose of learning when they ovulate so that they can time intercourse to optimize the chance of conception. Even C&D's internal research shows that there is strong demand for a pregnancy test that estimates when the woman ovulated – women want to know when they *conceived*, not when they last menstruated.

The fourth reason C&D's claim fails is that the alleged falsity is immaterial, and C&D therefore cannot show harm from the purported falsity. That is, if one were to assume (contrary to the only evidence on the subject) that women take away a false message that the Product estimates time from LMP rather than ovulation, there is no reason to believe this would make them *more* likely to buy the Product (and therefore less likely to buy C&D's products). Rather, all indications are that women want to know when they ovulated/conceived, so they would be *less* likely to buy the Product if they were deceived. Controlling law provides that, when the purported message is immaterial to the buying decision – and when the plaintiff has shown no harm from that purported message – a false advertising claim fails.

The evidence shows that C&D has never truly believed that advertising claiming that the Product estimates when women conceived is false. Indeed, C&D did nothing to challenge such claims for years when they were made in other countries where the two companies compete.

When C&D

saw that, unlike the authorities in other countries, the FDA had mandated limitations on marketing aimed at avoiding any confusion around different methods for pregnancy dating, C&D sought to exploit those restrictions into thwarting by litigation a Product for which it had no answer in the marketplace. Without knowing that the FDA had actually rejected C&D's

allegations and approved the challenged advertising, C&D launched this lawsuit. Once it learned of FDA's approvals, rather than dismissing its suit as it should have, C&D instead contorted the law and facts to try to create an actionable claim where there is none.

Finally, C&D has not even attempted to present evidence in support of its breach of contract claim. That claim should simply be dismissed prior to trial for failure of proof.

For all of these reasons, the Court should reject C&D's claims. They are barred by FDA action, utterly meritless and made in bad faith.

ARGUMENT

I. C&D's Claims Are Precluded By The FDA's Exercise Of Its Exclusive Authority Under The FDCA

A Lanham Act false advertising claim will be precluded when the claim being asserted directly conflicts with a fact-specific approval granted by the FDA in the exercise of its exclusive authority under the FDCA. *American Home Products Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 145 (S.D.N.Y 1987); *Cytyc Corp. v. Neuromedical Systems, Inc.*, 12 F. Supp. 2d 296 (S.D.N.Y. 1998); *SmithKline Beecham v Johnson & Johnson*, 1996 U.S. Dist. LEXIS 7257, *21 n.10, *41 (S.D.N.Y May 26, 1996) (court suggested that it would not substitute its "discretion for that of the FDA in approving package labeling for over-the-counter medications" by second-guessing the accuracy of those labels).

Here, C&D's claims directly conflict with the FDA's exhaustive and detailed review and control over the Weeks Estimator packaging, claims, and advertising. In considering SPD's clearance application for the Product, the FDA invoked Section 513(i)(1)(E) of the FDCA in order to control the packaging and promotional materials for the Weeks Estimator. In exercising that statutory authority, the FDA not only controlled every element of the Product packaging, but did so for the purpose of avoiding precisely the consumer confusion C&D alleges. (*See, e.g.,* DTX 001 [the "Hold Letter"] ("We have concerns that users misinterpret the weeks results to be

a substitution for gestational age determination or may misinterpret weeks results to mean they are pregnant and their pregnancy is progressing in a healthy manner..... Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitations must appear in the Indications for Use and in your device's labeling if your device is cleared.".) As a matter of law, those steps necessarily mean that FDA concluded that these marketing requirements were sufficient to prevent consumers from being confused and thereby harmed. 21 U.S.C. §360c(i)(1)(E)(ii)(III).

By challenging the Weeks Estimator advertising on the grounds that it misleads consumers into believing the Product is estimating weeks since LMP, C&D's claims collides with the FDA's determination that the disclosures it required on the packaging and all promotional materials were sufficient to avoid just such confusion. C&D's claims that the challenged advertising is misleading is a naked assault on the FDA's statutory judgment that the challenged message will not mislead consumers.

Just as this Court did in *American Home Products*, the Court should reject this effort. *American Home Products*, 672 F. Supp. at 145 (claim barred on preclusion grounds because the FDA had pre-approved the Anacin label fully cognizant of the specific risks of consumer confusion raised in McNeil's claims). A clearer case of "actual conflict" with a specific FDA judgment, exercised pursuant to express FDCA authority, is difficult to imagine.

II. C&D Cannot Meet Its Burden To Show False Advertising.

A. The Legal Standard.

Section 43(a) of the Lanham Trade-Mark Act, 15 U.S.C. § 1125(a), provides:

Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which--

(A) is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person, or

(B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities,

shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. § 1125(a).

To establish a false advertising claim under Section 43(a), the plaintiff must demonstrate that the statement in the challenged advertisement is false. "Falsity may be established by proving that (1) the advertising is literally false as a factual matter, or (2) although the advertisement is literally true, it is likely to deceive or confuse customers." *Nat'l Basketball Ass'n v. Motorola, Inc.*, 105 F.3d 841, 855 (2d Cir. 1997); *Johnson & Johnson * Merck Consumer Pharm. Co. v. Smithkline Beecham Corp.*, 960 F.2d 294, 297 (2d Cir. 1992).

The standard for a Section 349 claim is "substantially the same" as that for pleading a Lanham Act cause of action. *Gottlieb Dev. LLC v. Paramount Pictures Corp.*, 590 F. Supp. 2d 625, 636 (S.D.N.Y. 2008). Where a claim for false advertising fails under the Lanham Act, it likewise fails under Section 349 of the New York General Business Law. *Avon Products, Inc. v. S.C. Johnson & Son, Inc.*, 984 F. Supp. 768, 800 (S.D.N.Y. 1997) (denying false advertising claim under Section 349 "for the same reasons" as denying false advertising claim under the Lanham Act, noting that the standards under the Lanham Act are "substantially the same" as those applied to Section 349 of the New York General Business Law).

B. C&D Cannot Show That The Weeks Estimator Advertising Is Literally False.

According to C&D, the advertising for the Weeks Estimator is literally false because it

conveys to women that the product (i) estimates weeks since pregnancy began; and (ii) it provides an estimate of weeks the way a doctor does (i.e., from LMP).¹ C&D contends that such messages are false because the Product estimates weeks since a pregnant woman last ovulated, rather than weeks since a woman's LMP.

None of the challenged advertising contains any express claim that the Product estimates weeks since the start of pregnancy. While C&D might argue that such a message is necessarily implied from various elements of the advertising, the Court need not reach that issue. As explained below, any message that the Product estimates weeks since pregnancy began is true. C&D has failed to carry its burden that such a message is false or misleading.

With respect to the second purportedly false message, the challenged advertising contains no literal statement that the Weeks Estimator provides the same estimate as a doctor. Neither is such a statement necessarily implied by the advertising. In fact, the only literal messaging on this topic says the opposite – for example, the disclosure required by the FDA states, among other things, "Your doctor determines how many weeks pregnancy you are based on the first day of your last menstrual period and ultrasound results. This test provides a different estimate..." C&D, therefore, must supply survey evidence to show the existence of an implied message that the Product estimates the start of pregnancy according the medical convention of weeks since LMP.

1. C&D Cannot Show That, As A Matter of Biology, The Product Does Not Estimate The Number Of Weeks A Woman Has Been Pregnant.

It is C&D's burden to show that, as a matter of biology, the Product does not estimate the number of weeks a woman has been pregnant. It is uncontested that the Weeks Estimator

¹ C&D often conflates these two messages by assuming that an estimate of the start of pregnancy is, as a matter of "universal convention," an estimate based on LMP. As explained below, this is simply wrong.

estimates weeks since a pregnant woman last ovulated. As explained in the direct testimony of Dr. Kurt Barnhart and Dr. Sarah Johnson – and in the peer-reviewed articles they cite – time of ovulation represents not only a sound starting point for dating pregnancy, but the "gold standard" for such dating. (Direct Testimony of Kurt Barnhart, M.D., M.S.C.E. ("Barnhart DT") at ¶ 23; Direct Testimony of Dr. Sarah Johnson ("Johnson DT") submitted February 17, 2015 at ¶ 18.) Any message claim that the Product estimates weeks since start of pregnancy is literally true.

C&D's expert witness, Dr. Patrizio admits that pregnancy does *not* begin at LMP (Patrizio DT, ¶ 11), and he admits that "there is not a universally accepted 'biological' definition of the 'start of pregnancy'...." (Patrizio DT, ¶ 29.) Moreover, for the reasons explained in SPD's *Daubert* Motion to Exclude Testimony of Dr. Pasquale Patrizio, submitted on March 23, 2015, Dr. Patrizio's opinion that pregnancy begins at *implantation* of the egg in the uterus is entirely unfounded. Dr. Patrizio is C&D's only expert on issues of biology. Since he has failed to show that ovulation does not mark the start of pregnancy, C&D has failed to carry its burden of showing that the Product does not estimate weeks pregnant.

2. C&D Cannot Show That The Challenged Advertising Conveys The Implied Message That The Product Estimates Start Of Pregnancy According To The LMP Convention.

It is beyond reasonable dispute that the challenged advertising does not include any literal statement that the Weeks Estimator provides the same estimate as a doctor. Neither is such a statement implied by necessity. In fact, the only express language on this topic says the opposite: the statements on the box, in the package insert, and in the IFU found on all promotional materials say, among other things, that the Product "is not intended as a substitute for a doctor's clinical diagnosis," and "Your doctor determines how many weeks pregnancy you are based on the first day of your last menstrual period and ultrasound results. This test provides a different estimate..." (DTX 007; Johnson DT, ¶ 34.) C&D cannot credibly claim that the

challenged advertising conveys a literal message that the Product's estimate of weeks is the same as a doctor's estimate.²

Even if the challenged advertising did imply that the Product's estimate is the same as a doctor's estimate, C&D has failed to show that message is false. Doctors *do* estimate pregnancy based on ovulation, as explained in the direct testimony of Dr. Barnhart. (Barnhart DT, ¶ 15.) Indeed, Dr. Patrizio himself has admitted that "when the fertilization date (i.e., the date of ovulation) is known, the estimate of pregnancy duration is driven by *that* date and *not* the date of the pregnant woman's actual LMP. (Patrizio Dep. at 59:19-61:3.)

In order to prevail on a theory of implied falsity, C&D is therefore required to show that the advertising conveys the message that the Product estimates from LMP. As explained below, C&D has not even attempted to make this showing.

C. C&D Cannot Show That An Implied Message In The Weeks Estimator Advertising Misleads Consumers.

Where a plaintiff's theory of recovery is premised upon a claim of implied falsehood, a plaintiff must demonstrate, by extrinsic evidence, that the challenged commercials tend to mislead or confuse consumers. *Smithkline*, 960 F.2d at 297. "It is not for the judge to determine, based solely upon his or her own intuitive reaction, whether the advertisement is deceptive. Rather, as we have reiterated in the past, "[t]he question in such cases is—what does the person to whom the advertisement is addressed find to be the message?" That is, what does the public

² Even if the challenged advertising did imply that the Product's estimate is the same as a doctor's estimate, C&D has failed to show that message is false. Doctors *do* estimate pregnancy based on ovulation, as explained in the direct testimony of Dr. Barnhart. (Barnhart DT, ¶ 15.) Indeed, Dr. Patrizio himself has admitted that "when the fertilization date (i.e., the date of ovulation) is known, the estimate of pregnancy duration is driven by *that* date and *not* the date of the pregnant woman's actual LMP. (Patrizio Dep. at 59:19-61:3.) C&D cannot meet its burden to show that a (nonexistent) claim that the Product provides the same estimate as a doctor is false.

perceive the message to be?" *Id.* at 297-98 (internal citations omitted); *American Home*, 577 F.2d at 165 ("The question in such cases is what does the person to whom the advertisement is addressed find to be the message?").

"In determining whether an advertisement is misleading, the Court must first consider its literal meaning, then determine whether it conveys to the particular audience at which it was directed any implied message beyond its literal meaning." *American Home Products Corp. v. Johnson & Johnson*, 654 F. Supp. 568, 590 (S.D.N.Y. 1987). "Once the meaning of the advertisement to the target audience has been determined, the Court, as the finder of fact, must then judge for itself whether the evidence establishes that readers are likely to be misled." *Id.*

The meaning of an advertisement to its target audience may be established by properly designed and conducted surveys. *Id.* Indeed, the success of a plaintiff's implied falsity claim usually turns on the persuasiveness of a consumer survey. *Smithkline*, 960 F.2d at 298. See *Coca-Cola Co. v. Tropicana Products, Inc.*, 690 F.2d 312, 317 (2d Cir. 1982) ("When the challenged advertisement is implicitly rather than explicitly false, its tendency to violate the Lanham Act by misleading, confusing or deceiving should be tested by public reaction."); *McNeil-PPC, Inc. v. Pfizer Inc.*, 351 F. Supp. 2d 226, 249 (S.D.N.Y. 2005) ("Typically, an implied claim is proven through the use of a consumer survey that shows a substantial percentage of consumers are taking away the message that the plaintiff contends the advertising is conveying.").

"The probative value of a survey depends entirely upon its fundamental fairness and objectivity, which in turn depends upon many factors, such as whether it is properly 'filtered' to screen out those who got no message from the advertisement, whether the questions are directed to the real issues, and whether the questions are leading or suggestive." *American Home Products Corp. v. Johnson & Johnson*, 654 F. Supp. 568, 590 (S.D.N.Y. 1987).

To do make the necessary showing of implied falsity, C&D must prove that "a substantial percentage of consumers are taking away the message that the plaintiff contends the advertising is conveying." *McNeil-PPC*, 351 F. Supp. 2d at 249. That is, C&D must prove that the messages in the challenged advertising are impliedly false because such messages convey or imply to consumers that the Product estimates when pregnancy started according to the convention counting weeks since LMP. This required showing of implied falsity is typically made through a consumer survey. *Id.*

As explained in SPD's *Daubert* Motions to Exclude Testimony of Dr. Bruce Isaacson and Mr. Hal Poret, submitted on March 23, 2015, C&D has failed to make this showing. Among the other reasons explained in SPD's motions, C&D's survey experts' analyses were based on the unjustified assumption that women believe that weeks of pregnancy are conventionally measured by doctors from LMP.

D. C&D Cannot Show That The Allegedly False Message Is Material To Consumers.

In addition to proving falsity, the plaintiff must also show that the defendants "misrepresented an 'inherent quality or characteristic' " of the product. *NBA*, 105 F.3d at 855. "This requirement is essentially one of materiality, a term explicitly used in other circuits. See *American Tel. & Tel. Co. v. Winback and Conserve Program, Inc.*, 42 F.3d 1421, 1428 n. 9 (3d Cir.1994) (plaintiff alleging false advertising must prove "that the deception is material in that it is likely to influence purchasing decisions") (citations and internal quotation marks omitted), cert. denied, 514 U.S. 1103, 115 S.Ct. 1838, 131 L.Ed.2d 757 (1995); *ALPO Petfoods, Inc. v. Ralston Purina Co.*, 913 F.2d 958, 964 (D.C.Cir.1990) (false or misleading ads must be "material in their effects on buying decisions"); *Taquino v. Teledyne Monarch Rubber*, 893 F.2d 1488, 1500 (5th Cir.1990) (deception must be "material, in that it is likely to influence the purchasing decision"); see also 3 McCarthy on Trademarks § 27:35 at 27–54 (there must be

"some showing that the defendant's misrepresentation was 'material' in the sense that it would have some effect on consumers' purchasing decisions."")." *Id.*

C&D has no evidence that the alleged falsity affects buyers' decision-making. As explained in SPD's *Daubert* Motion to Exclude Testimony of Dr. Tulin Erdem, submitted on March 23, 2015, C&D has failed to do this. Women want to know when they *conceived*, not when they last menstruated. The truth – that the Product estimates from ovulation – is much more likely to drive sales than the alleged deception – that the Product will estimates weeks since LMP. Dr. Erdem made no effort at all to show that sales are more likely to be diverted from C&D by virtue of the purported message that the Product estimates weeks since LMP. C&D therefore fails to sustain its burden of showing materiality.

E. C&D Cannot Show A Logical Causal Connection Between The Alleged False Messages Purportedly Conveyed By The Weeks Estimator Advertisings And Any Economic Harm To C&D.

Although Section 43(a) affords a claim to a plaintiff who "believes that he or she is or is likely to be damaged" by the challenged act, something more than a plaintiff's mere subjective belief that he is injured or likely to be damaged is required before he will be entitled even to injunctive relief. *Johnson & Johnson v. Carter-Wallace, Inc.*, 631 F.2d 186, 189 (2d Cir. 1980). A plaintiff must submit proof that will establish a "reasonable basis for belief" that the plaintiff is "likely to be damaged" as a result of the false advertising. *Carter-Wallace*, 631 F.2d at 190. The "likelihood of injury and causation will not be presumed, but must be demonstrated in some manner." *Coca-Cola Co. v. Tropicana Products, Inc.*, 690 F.2d 312, 316 (2d Cir. 1982).

To prove a likelihood of injury when seeking injunctive relief, the plaintiff must "show a logical causal connection between the alleged false advertising and its own sales position." *Johnson*, 631 F.2d at 190; *McNeilab, Inc. v. American Home Products Corp.*, 848 F.2d 34, 38 (2d Cir. 1988) ("some indication of actual injury and causation to satisfy Lanham Act standing

requirements and to ensure a plaintiff's injury was not speculative."); *Ortho Pharm. Corp. v. Cosprophar, Inc.*, 32 F.3d 690, 695 (2d Cir. 1994) (dismissing false advertising claims where consumer surveys submitted below "did not establish a causal link between [defendant's] advertisements and any damage claimed by Ortho because they merely corroborated" undisputed facts). It is not sufficient for the plaintiff to show a link between the advertising generally and the purported harm. Rather, what's relevant is the causal connection between the harm and the allegedly false message communicated or conveyed by the challenged advertising. *Procter & Gamble Co. v. Ultreo, Inc.*, 574 F. Supp. 2d 339, 350 (S.D.N.Y. 2008) (denying injunctive relief in Lanham Act false advertising case, where the proffered market study failed to establish "a logical causal connection between the alleged false advertising and [plaintiff's] own sales position" because it failed to distinguish between loss of sales due to alleged false advertising versus truthful advertising).³

Even if the Court finds that the challenged advertising is false – either literally or impliedly so – C&D must establish a logical causal connection or link between the false or misleading messages conveyed by the advertising and any harm it proves it has suffered. Again, as explained in SPD's *Daubert* Motion to Exclude Testimony of Dr. Tulin Erdem, submitted on March 23, 2015, C&D has failed to do this. This is because, among the other reasons addressed in SPD's motion, Dr. Erdem's opinion of harm rests on an unsupported and unexamined assumption: that women view weeks of pregnancy to mean weeks since LMP.

³ Where damages are sought, more proof is required. *Carter-Wallace*, 631 F.2d at 190 ("If such a showing is made, the plaintiff will have established a reasonable belief that he is likely to be damaged within the meaning of s 43(a) and will be entitled to injunctive relief, as distinguished from damages, which would require more proof.").

III. C&D Has Offered Exactly Zero Evidence In Support Of Its Breach Of Contract Claim, And It Should Be Dismissed Out of Hand.

"Pursuant to New York law, the elements of a breach of contract claim are 'the existence of a contract, the plaintiff's performance thereunder, the defendant's breach thereof, and resulting damages.'" *Russo v. Estee Lauder Corp.*, 856 F. Supp. 2d 437, 460 (E.D.N.Y. 2012) (citing *Harris v. Seward Park Housing Corp.*, 913 N.Y.S.2d 161, 162 (N.Y.App.Div.2010)).

"The interpretation of a contract is a matter of law for the court." *Russo*, 856 F. Supp. 2d at 460 (citing *1550 Fifth Ave. Bay Shore, LLC v. 1550 Fifth Ave., LLC*, 748 N.Y.S.2d 601, 603 (N.Y.App.Div.2002)).

"Under New York law, for a breach of a contract to be material, it must "go to the root of the agreement between the parties." *Frank Felix Associates, Ltd. v. Austin Drugs, Inc.*, 111 F.3d 284, 289 (2d Cir. 1997). "A party's obligation to perform under a contract is only excused where the other party's breach of the contract is so substantial that it defeats the object of the parties in making the contract." *Frank Felix*, 111 F.3d at 289.

Under New York law, a duty of good faith and fair dealing is implied in every contract. *National Mkt. Share, Inc. v. Sterling Nat. Bank*, 392 F.3d 520, 525 (2d Cir. 2004). The duty comprises "any promises which a reasonable person in the position of the promisee would be justified in understanding were included [in the contract]." *Id.* (citing *Dalton v. Educ. Testing Serv.*, 87 N.Y.2d 384, 389 (1995)). "Where the contract contemplates the exercise of discretion, this pledge includes a promise not to act arbitrarily or irrationally in exercising that discretion." One party's discretion cannot "go so far as to enable the party to eviscerate [a] term [of the contract] and frustrate a fundamental purpose underlying the agreement. *TIG Ins. Co. v. Newmont Min. Corp.*, 413 F. Supp. 2d 273, 281 (S.D.N.Y. 2005) aff'd, 226 F. App'x 49 (2d Cir. 2007).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

IV. C&D's Claim For Injunctive Relief Should Be Denied Due To C&D's Unclean Hands.

"Because a court sitting in equity is a vehicle for affirmatively enforcing the requirements of conscience and good faith, a party who comes into equity must come with clean hands if relief is to be granted." *Gidatex, S.r.L. v. Campaniello Imports, Ltd.*, 82 F. Supp. 2d 126, 130 (S.D.N.Y. 1999) (internal citations omitted); *Hermes Int'l v. Lederer de Paris Fifth Ave., Inc.*, 219 F.3d 104, 107 (2d Cir. 2000). The unclean hands defense applies to false advertising claims under the Lanham Act. *Stokely*, 646 F. Supp. 2d at 532 (S.D.N.Y. 2009). The defendant who invokes the doctrine of unclean hands has the burden of proof. *Gidatex*, 82 F. Supp. 2d at 130.

A court may deny injunctive relief based on the defense of unclean hands "where the party applying for such relief is guilty of conduct involving fraud, deceit, unconscionability, or bad faith related to the matter at issue to the detriment of the other party." *Estate of Lennon by Lennon v. Screen Creations, Ltd.*, 939 F. Supp. 287, 293 (S.D.N.Y. 1996); *Stokely*, 646 F. Supp. 2d at 533 (S.D.N.Y. 2009) (precluding on unclean hands grounds false advertising claims brought by SVC, the maker of Gatorade, relating to Coca-Cola's alleged touting of calcium and magnesium, where Coca-Cola claimed that "SVC too planned to introduce a new formulation of Gatorade with calcium and magnesium").

By seeking to challenge the Weeks Estimator advertising [REDACTED]

[REDACTED] and only challenging the claims made in the U.S. in the hope of piggybacking on the FDA's constraints, C&D's claims are precluded by its own unclean

hands, which bad faith is related to the subject matter of its claims.

CONCLUSION

C&D's false advertising claims are barred by FDCA preclusion as it directly conflicts with the FDA's control and approval of the challenged advertising message. Even if that were not the case, to prevail on its Lanham Act and related state law claims, C&D must show that the challenged advertising conveys either a literally false or impliedly false message. C&D cannot begin to sustain that burden. In addition, it must also prove that there is a logical causal connection between any false messages and any economic harm that it can prove it has suffered. This too it has failed to do. C&D's request for injunctive relief is separately barred under the doctrine of unclean hands. Finally, C&D has offered no competent testimony to support its breach of contract claim.

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Respectfully submitted,

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